

REMARKS

Applicants respond to the December 9, 2003 Office Action and to the Advisory Action mailed June 10, 2004. The December 9, 2003 Office Action has asked for cancellation of non-elected claims and has rejected the two pending claims under 35 U.S.C. § 102. The June 10, 2004 Advisory Action asks for a signed declaration of Karen M. Downs. In light of the amendments above and the arguments below Applicants respectfully request reconsideration.

On June 9, 2004 Applicant filed a Notice of Appeal. However, Applicant believes that outstanding issues can be resolved by the present submission.

Context of Response

This submission essentially duplicates the response submitted April 23, 2004 to the December 9, 2003 Office Action in which Applicants addressed the Examiner's 35 U.S.C. § 102 rejection. Applicants had amended claim 27 to depend from new claim 30 and had added new claim 30.

The June 10, 2004 Advisory Opinion indicates that "proposed claims 27 and 30 will not be entered. The proposed claim would require a rejection under 102(a)

using Downs, November 1998. It is noted that Applicants preemptively filed the Katz Declaration over Downs, November 1998 to prevent such a rejection. However, the declaration is defective because it is unsigned. This informal matter cannot be addressed in a Quayle type allowance because the 102(a) rejection has not been made." (Bottom of page 2 of the June 10, 2004 Advisory Opinion.) Applicants point out that their April 23, 2004 response did contain a signed declaration, a copy of which is enclosed. To expedite matters, Applicants have submitted a second signed Declaration of Karen M. Downs. This declaration is identical to the one submitted April 23, 2004 except that it specifically enumerates the other authors of Downs 1998. Applicants believe that this pair of *In re Katz* Declarations overcome the pending § 102 rejection over Downs 1998. The Advisory Action notes that "proposed claim 30 would overcome the pending 102 rejection over Downs 1995," which was the only pending rejection in the Office Action. Applicants below have recreated the response to the December 9, 2003 Office Action so that this response will be complete without reference to Applicant's response of April 23, 2004.

Election/Restriction

As the December 9, 2003 Office Action requested, Applicants have now formally cancelled claims 1 - 13, 15, 16, 18, 28 and 29. The only claims pending are claim 27 and new claim 30.

Claim Rejection Under 35 U.S.C. § 102

The December 9, 2003 Office Action has rejected claims 27 and 28 under 35 U.S.C. § 102(b) as being anticipated by Downs (February, 1995 Development, Vol. 121, pages 407-416) for reasons of record. The Office Action has asserted that the Downs 1995 reference inherently demonstrates the isolation of allantoic tissue, culturing the tissue *in vitro*, treating the allantoic tissue with a test compound and observing vasculogenesis. Applicants have argued that neither Applicant nor anyone else could have understood that vasculogenesis was being observed and that Applicant had inadvertently used the word "vasculogenesis" when "vascularization" was more correctly meant in the reference. Applicants have also argued that the Downs, 1995 reference does not demonstrate the application of a "test compound" to allantoic tissue. Examiner Wilson has not accepted these arguments.

While still continuing to assert that the claims of the present invention are not inherently taught by the Examiner's reference, Applicants wish to emphasize claim language that Applicant believes distinguishes the reference even if the method, as Examiner Wilson postulates, was inherently disclosed in Downs, 1995.

Applicant points to step (d) of new claim 30 where Applicant had noted that one would observe blood vessel formation originating in the allantoic tissue, wherein an "alteration in the development of allantoic mesoderm into blood vessels in the first allantoic tissue as compared to the second allantoic tissue indicates that the compound alters the development of allantoic mesoderm into blood vessels." Applicant notes that this comparison of allantoic tissue treated with a test compound and not treated with a test compound cannot be found in the Downs, 1995 disclosure. To further emphasize this limitation, Applicant has added language to (a) and (b) to further clarify that an identical allantoic tissue that is not treated with the test compound is provided and observed.

Applicant notes to Examiner Wilson that this language was already in the claim and Applicant is simply making a clarification.

Additionally, Applicant has clarified the definition of vasculogenesis as characterized by mesoderm cells which differentiate into blood vessels (specification page 16, lines 1 - 10). In a previous conversation, Examiner Wilson had suggested that Applicants insert language into the claim that clarify the difference between "vasculogenesis" and "vascularization."

Applicants believe that Downs, 1995 has been removed as a § 102(b) reference.

Examiner Wilson's draft response to Applicant's proposed claim indicated that the Examiner questioned whether the claim language was fully disclosed in the earliest provisional application claiming priority for the above-identified case. Examiner Wilson notes that "Downs, 1998 will have to be considered . . ." Applicant does not agree that the earliest provisional application does not disclose current claim language, but, in the risk of speedy prosecution and Applicant's stated goal of bringing the currently pending claims to allowance in this Office Action, Applicants have enclosed an *In Re*

Appl. No. 09/336,103  
Amdt. Dated June 21, 2004  
Reply to Advisory Opinion of June 10, 2004

Katz Declaration showing that the authors of Downs, 1998 are the same inventors of the above-identified application. Applicants note that Downs, 1998 is published within a year of the above-identified filing date, June 18, 1999.

Applicant believes that the claims are in condition for allowance and respectfully request allowance.

Respectfully submitted,

Karen M. Downs

June 21, 2004

By: 

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I hereby certify that this correspondence is being deposited with the United States Postal Services on the date set forth below as First Class Mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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6/21/04

*[Signature]*  
Attorney of Record

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Karen M. Downs  
Serial No.: 09/336,103  
Filed: June 18, 1999  
For: CHIMERIC MAMMALIAN ALLANTOIS  
Group Art Unit: 1632  
Examiner: M. Wilson

Commissioner For Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

DECLARATION OF KAREN M. DOWNS

Dear Sir:

I, Karen M. Downs, am the named inventor of the above-identified application and one of the authors of Downs, 1998 (Development 125, 4507-4520, 1998). The other authors of Downs, 1998 (Shannon Gifford, Melanie Blahnik, and Richard Gardner) contributed to the publication but did not contribute to the above-identified invention.

I note that the publication date of Downs, 1998 is 20 October 1998, which is less than a year before the June 18, 1999 filing date referenced above.

I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and

further that these statements were made with the knowledge that willful false statements and the like made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the above-identified application or any patent issuing thereon.

Dated: June 16, 2004

Respectfully submitted,

Karen M. Downs  
Karen M. Downs





I hereby certify that this correspondence is being deposited with the United States Postal Services on the date set forth below as First Class Mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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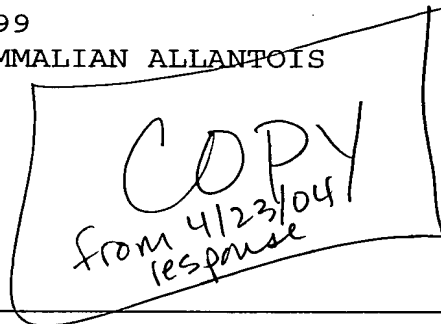
*Jan C. Baber*

Attorney of Record

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Karen M. Downs  
Serial No.: 09/336,103  
Filed: June 18, 1999  
For: CHIMERIC MAMMALIAN ALLANTOIS  
Group Art Unit: 1632  
Examiner: M. Wilson

Commissioner For Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450



DECLARATION OF KAREN M. DOWNS

Dear Sir:

I, Karen M. Downs, am the named inventor of the above-identified application and one of the authors of Downs, 1998 (attached). The other authors of Downs, 1998 contributed to the publication but did not contribute to the above-identified invention.

I note that the publication date of Downs, 1998 is 20 October 1998, which is less than a year before the June 18, 1999 filing date referenced above.

I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like made

are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the above-identified application or any patent issuing thereon.

Respectfully submitted,

Dated: \_\_\_\_\_

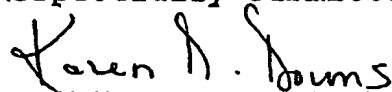
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Karen M. Downs

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Appl. No. 09/336,103  
Amdt. Dated April 23, 2004  
Reply to Office Action of December 9, 2003

Section 1001 of Title 18 of the United States Code and  
that such willful false statements may jeopardize the  
validity of the above-identified application or any  
patent issuing thereon.

Respectfully submitted,

  
\_\_\_\_\_  
Karen M. Downs

Dated: